significantly (p = 0.0432) higher costs for cilostazol using a gamma GLM model. **CONCLUSIONS:** The gamma GLM technique is a powerful tool for modeling strictly positive skewed outcomes and should be more widely employed in pharmacoeconomic analyses.

PMD2

MONTE-CARLO VALIDATION OF DELTA-K METHOD FOR SAMPLE-SIZE CALCULATION IN A COST-EFFECTIVENESS TRIAL

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To design a cost-effectiveness trial, the Delta-K method newly developed provides us with a new formula for sample-size calculation. The Delta-K utilizes the difference between two cost-effectiveness ratios, q_A and q_B, respectively of control and experimental regimens (i.e., $K_D = 1/q_A - 1/q_B$). The advantage of the method is simplicity for estimating the sample-size, naturally extending the conventional binomial formula, whereas under the assumption of "econstant" cost for each regimen. **OBJECTIVES:** Using multivariate analysis with the Monte-Carlo simulation for "evariable" costs, we assess the robustness of the Delta-K method in search of the probable range of sample-sizes calculated based on the formula. **METHOD:** A case study of cost-consequence analysis is employed to validate the design of a clinical trial, which evaluates herpes zoster treatment with Valaciclovir vs. Aciclovir. Our former investigation on this case illuminated that the sample-size for the RCT could be reduced from n = 821 to n = 36 in use of the Delta-K method regarding the average costs as constant. In the Monte-Carlo simulation, therefore, the three major factors of costs such as primary medication, treatment for post herpes neuralgia (PHN), and outpatient care were assumed to have a normal distribution since each factor is quantified with the mean and the standard deviation (S.D.)(e.g., for PHN; US$1504.9 ± 6.1 in Valaciclovir, whereas US$2006.6 ± 6.6 in Aciclovir). Under these conditions Monte-Carlo simulation was run up to 10,000 times to assess the overall distribution of sample-sizes calculated from the formula. **RESULTS:** The runs of 10,000 times resulted in the distribution with the sample-size of 35.2 ± 0.8(the mean ± 2S.D.) and the range of (33.7, 37.0) = (min, max), which is far smaller than the original sample-size n = 821. **CONCLUSION:** We confirmed sufficient robustness of the Delta-K method in a case study even if medical costs vary against the assumption of constant cost. It suggests the usefulness of the new method.

PMD3

INCREMENTAL COST EFFECTIVENESS RATIOS AND CONFIDENCE INTERVALS—RELATIONSHIP OF CALCULATIONS WITH NNT VERSUS BOOTSTRAP METHODS

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The concept of incremental cost effectiveness ratios (ICERs) and confidence intervals (CIs) may seem complicated to many practitioners and decision makers. There is a growing body of literature regarding the use of NNT (number needed to treat) as a statistic that may be easier to understand in clinical practice. NNTs and ICERs are receiving increased attention in the interface of clinical and economic concepts. **OBJECTIVE:** To compare the ICER and CI results by using NNT-related calculations versus bootstrap analyses utilizing datasets from three published papers. **METHODS:** An NNT spreadsheet calculator was developed that generates NNT confidence intervals and incremental cost to treat calculations. Datasets with an aggregate total of over 2000 patients from three previously published pharmacoeconomic studies were analyzed with both the NNT and bootstrap ICER approach. The NNT calculator used a two by two contingency table with additional cells for including cost of each treatment. Confidence intervals (95%) were calculated for NNT and the upper and lower values of the incremental cost per successfully treated patient. In contrast, the bootstrap software utilizes each individual patient case in the datasets to generate ICER ratios and ICER confidence intervals. **RESULTS:** The NNT results for the mean cost needed to treat for one successful outcome showed good agreement with the bootstrap generated ICER slopes. For NNT versus bootstrap, the anti-platelet study mean ICERs were $43,729 vs. $43,742, the antidepressant comparative study ICERs were –$1648 vs. –$1647 and the antidepressant combination study ICERs were –$188,014 vs. –$188,012. Using 5th and 95th percentiles for cost of treatment multiplied by corresponding NNT confidence intervals did not generate very close agreement with the bootstrapped CIs. **CONCLUSIONS:** NNT related calculations may be a method for initially analyzing local pilot data or explore the economic ramifications of a clinical publication when the full dataset is not available.

PMD4

ISHIKAWA CAUSE AND EFFECT DIAGRAMS: A USEFUL TOOL IN DESIGNING ECONOMIC ANALYSES

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OBJECTIVES: Cause and effect diagrams (also known as Ishikawa or fishbone diagrams) graphically depict the relationships between a particular outcome and all of the identified factors contributing to that outcome. The diagram's structure includes a central "bone" with the topic of interest (the "head") attached at the right-hand end. Branching out from the central line are "sub-bones" that represent primary causal factors, and each of these in turn has sub-bones representing subsidiary contributing factors. **METHODS:** Ishikawa diagrams were originally developed and have typically been used as a tool for root cause analyses, but they also can benefit the planning of economic analyses for a particular disease state, medical technology, or other health care intervention. Recent projects conducted by the Department of Health Policy of Jefferson Medical College illustrate the value of Ishikawa diagrams in planning economic analyses. One project involved the development of an economic model related to the diagnosis and management of Crohn's disease. An Ishikawa diagram was used to organize the findings of an extensive literature review on this topic. The main categories, or "sub-bones" contributing to the cost of Crohn's included: diagnostic work-up, medication therapy, administration, hospitalization, surgery, and adverse reactions/complications. **RESULTS:** Many of these categories were further broken down into appropriate subcategories. In another project, this tool was used to organize and graphically depict cost factors for allogeneic blood transfusions. Identified factors contributing to total costs were organized around four main sub-bones: Acquisition, Administration, Preparation, and Adverse Events/Complications. **CONCLUSIONS:** In both of these projects, the constructed diagram facilitated the organization of large amounts of information, selection of key factors for inclusion in decision analytic economic models, and identification of unmeasured contributors to cost, which might influence the model's assumptions or findings. Outcomes researchers therefore are